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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ASEA/AFSCME Local 52 Health Benefits Trust, and Claudia Edwards, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

MERCK & CO., INC.; SCHERING-PLOUGH CORPORATION; and MERCK/SCHERING-PLOUGH PHARMACEUTICALS,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

JL

I. INTRODUCTION

1. This class action is brought by Plaintiffs ASEA/AFSCME Local 52 Health Benefits Trust ("ASEA") and Claudia Edwards on behalf of themselves and Classes of similarly situated individuals and entities to recover billions of dollars they paid to Defendants as a result of Defendants' fraudulent marketing and promotion of Zetia and Vytorin, two drugs jointly marketed and sold by

Defendants Merck & Co., Inc. ("Merck"), Schering-Plough Corporation ("Schering-Plough"), and Merck/Schering-Plough Pharmaceuticals ("MSP"). ASEA is a self-funded health benefit trust providing health care coverage to employees of the State of Alaska who are members of the General Governmental Union represented by ASEA/AFSCME Local 52. The Trust is domiciled in Spokane, Washington. Edwards is a resident of San Diego, California.

2. Defendants Merck and Schering-Plough are global pharmaceutical companies. Defendant MSP is a joint venture partnership between Merck and Schering-Plough formed as a result of agreements Merck and Schering-Plough entered into in May 2000 to develop and market cholesterol-lowering pharmaceuticals.

3. Defendants developed and marketed Zetia and Vytorin for the treatment of high cholesterol. Unlike statins, which have long been accepted as safely lowering cholesterol and reducing the risk of heart attacks and strokes, and which work by interfering with the manufacturing of cholesterol in the liver, Zetia is purported to block the absorption of cholesterol in the intestinal tract, and has not been shown to reduce heart attacks. Defendants promoted Zetia's use as a single cholesterol-lowering agent, and promoted its use with statins, as separate medications and together in Vytorin. Vytorin combined Zetia and Zocor, a statin developed and marketed by Defendant Merck.

4. In April 2006, Defendants concluded a study designed to test the effect of Vytorin (Zetia and Zocor together) versus Zocor alone on the growth of fatty plaque in the arteries on individuals with high cholesterol. The study showed that Vytorin was ineffective in reducing fatty plaque in the arteries. In fact the Vytorin group had a greater change in carotid artery intima-media thickness (CA IMT) than the Zocor-alone group. With knowledge of this study's results, Defendants delayed the release of this study until January 14, 2008, while continuing to tout Vytorin's and Zetia's safety and effectiveness.

5. From the time the study concluded, to the belated release of its results, Defendants reaped significant financial rewards from Zetia and Vytorin. Zetia's 2006 sales were $1.93 billion; Vytorin's 2006 sales were $1.96 billion. Defendants were estimated to earn approximately $5 billion from combined sales of Zetia and Vytorin in 2007.

6. Plaintiff Edwards seeks to represent a class of consumers who paid for Vytorin and/or Zetia from April 1, 2006 to the present ("the Class period"). Plaintiff ASEA seeks to represent a class of third-party payers who paid for Zetia and Vytorin during the Class period.

II. PARTIES

7. Plaintiff Claudia Edwards is a resident of California. During the Class Period, Plaintiff Edwards was prescribed and used Vytorin. Ms. Edwards paid up to $60 for thirty tablets of Vytorin, which were prescribed to be taken once per day. Ms. Edwards, who began taking Vytorin in February 2006, ceased taking it after reading of the results of the study on Vytorin and Defendants' delay in releasing those results.

8. Plaintiff ASEA/AFSCME Local 52 Health Benefits Trust was created through collective bargaining between the State of Alaska and ASEA/AFSMCE Local 52 to provide reimbursement for eligible health, vision, dental and prescription drug claims incurred by employees of the State of Alaska who are members of the General Governmental Unit represented by ASEA/AFSCME Local 52. At various times during the Class period, ASEA paid or reimbursed eligible Trust participants' prescription drug benefits for Zetia and Vytorin in Alaska and elsewhere other than for resale and was injured by the illegal conduct alleged herein, incurring substantial losses as a result of these payments.

9. Merck is a corporation incorporated and headquartered in New Jersey. It reported global sales of $22.6 billion for 2006, and $18 billion through the first three quarters of 2007.

10. Schering-Plough is a corporation incorporated and headquartered in New Jersey. Schering-Plough reported net sales of $10.6 billion for 2006.

11. Merck/Schering-Plough Pharmaceuticals ("MSP") is a joint venture partnership between Merck and Schering-Plough. MSP's headquarters are in North Wales, Pennsylvania. In May 2000, Merck and Schering-Plough entered into agreements to create separate equally-owned partnerships to develop and market in the United States new prescription medicines in the cholesterol-management and respiratory therapeutic areas. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company, and provide for the sharing of operating income generated by the Merck/Schering-Plough cholesterol partnership based

upon percentages that vary by product, sales level and country. In the U.S. market, Merck and Schering-Plough share profits on Zetia and Vytorin sales equally, with the exception of the first $300 million of annual Zetia sales, on which Schering-Plough receives a greater share of profits. An additional jointly-owned, limited purpose legal entity based in Singapore was established to own the rights to the intellectual property of MSP and to fund and oversee research and development and manufacturing activities of MSP and certain respiratory products.

III. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and 28 U.S.C. § 1964(c), because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

13. This Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over the violations of the New Jersey Consumer Fraud Act, the Uniform Deceptive Trade Practices Act, and Plaintiffs' claims of common law fraud and unjust enrichment.

14. This Court has personal jurisdiction over Defendants because a substantial portion of the wrongdoing alleged in this Complaint took place in this state, Defendants are authorized to do business here, Defendants have sufficient minimum contacts with this state, and/or Defendants otherwise intentionally avail themselves of the markets in this state through the promotion, marketing and sale of its products in this state, to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965. A substantial part of the events and omissions giving rise to the claims alleged in this Complaint occurred in this district. Defendants implemented their fraudulent and deceitful scheme in this district, as well as nationwide, through print, television, and radio media disseminated in this district, and on Class members who reside in this district. Defendants are subject to personal jurisdiction in this district for the reasons stated in Paragraph 14.

IV. INTRA-DISTRICT ASSIGNMENT

16. Given the relative populations of the San Francisco/Oakland and San Jose districts, a substantial part, and the greater proportion of, the wrongs giving rise to the claims asserted in this Complaint occurred in the San Francisco/Oakland district, providing the basis for assignment to that district.

V. FACTUAL ALLEGATIONS

A. Background: Zetia and Vytorin

17. The cholesterol-reduction market is the single largest pharmaceutical category in the world.

18. Zetia is the brand name for ezetimibe, marketed and sold through Defendant MSP, the joint venture between Merck and Schering-Plough. It was approved by the Food and Drug Administration ("FDA") on October 25, 2002 for the reduction of cholesterol. Zetia can be taken alone, with statins, or in Vytorin, a single pill combining one type of statin and Zetia. Zetia's global sales were $1.93 billion in 2006, and $1.40 billion in 2005.

19. Zetia's purported mechanism of action is different than that of statins, which have been marketed since 1987. Statins work by interfering with the manufacturing of cholesterol in the liver, and are widely accepted to be effective in safely lowering cholesterol and reducing the risk of heart attacks. By contrast, Defendants have promoted Zetia as "a different way to help fight cholesterol," by blocking the absorption of cholesterol in the intestines. Zetia has never been proven to reduce heart attacks. Zetia is often prescribed with low-dose statins; high doses of statins have been associated with muscle pain.

20. Zocor is the brand name for one type of statin (simvastatin), and is also used to lower cholesterol. It was developed by Defendant Merck, which lost patent exclusivity on it in the United States in June 2006. Zocor's 2006 sales were $2.8 billion, down 38% from 2005.

21. Vytorin is the brand name for a single pill combining Zetia and Zocor. It is also jointly marketed by Merck and Schering-Plough. Vytorin was approved by the FDA for marketing in the U.S. in July 2004. About 60 percent of patients who take Zetia do so in the Vytorin form. Global sales of Vytorin were $1.96 billion in 2006, an increase of 96% from $1.0 billion in 2005.

22. Unlike Zocor, which is now subject to competition from generic simvastatins, Zetia and Vytorin command name-brand prices. Despite their high costs relative to available generic statins, Zetia and Vytorin represent nearly 20 percent of the American market for cholesterol-lowering drugs, with projected sales of $5 billion in 2007 from Zetia and Vytorin. 800,000 prescriptions for Zetia and Vytorin are written weekly in the U.S.

23. Zetia and Vytorin are particularly crucial to Schering-Plough's business. Indeed, Schering-Plough's most recent 10-K filing with the Securities and Exchange Commission stated, "Schering-Plough's ability to generate profits and operating cash flow is largely dependent upon the continued profitability of Schering-Plough's cholesterol franchise, consisting of VYTORIN and ZETIA."

B. The Enhance study

24. In 2004, Merck and Schering-Plough began a two-year study to compare the effects of Vytorin (Zetia and Zocor) versus Zocor (statins) alone on the growth of fatty plaque in the arteries, a risk factor for heart attacks and strokes. The study, an international, randomized, controlled clinical trial conducted on 720 European patients with genes that cause abnormally high cholesterol levels, was titled "Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression," termed "ENHANCE" by Defendants.

25. The growth of fatty plaque on the arteries, called atherosclerosis, is, according to the authors of the study, "the disease process underlying most cardiovascular events," and can be caused by hyperlipidemia, or high cholesterol.

26. The primary endpoint of the Enhance study was the effect, over two years, of Vytorin (Zetia + Zocor) and Zocor alone on carotid artery intima-media thickness (CA IMT), "a well-validated measure of atherosclerosis that has been shown to correlate well with cardiovascular and cerebrovascular events." The study was designed to test the hypothesis that treatment of high cholesterol by Zetia and Zocor together will result in larger beneficial effects on CA IMT than Zocor alone. The study concluded in April 2006.

27. It would be almost two years later that Defendants released the results of the Enhance study, who did so under pressure, only after the delay caught the attention of the national press and Congress.

C. Results of the Enhance Study

28. On January 14, 2008, Defendants belatedly announced the results of the Enhance study. The study showed that Vytorin group did not have a lower CA IMT than the Zocor-alone group. In fact, the Vytorin group's CA IMT was thicker than the Zocor-alone group.

29. Although Merck/Schering-Plough stated in a press release that there was no statistically significant difference between treatment groups on the primary endpoint (the mean change in the IMT at three sites in the carotid arteries), the group treated with statins alone showed a mean carotid IMT of 0.0058 mm, while the group treated with Zetia and statins showed a mean carotid IMT of almost double that of the statins monotherapy group: 0.0111 mm. The fatty plaque of those who had taken Vytorin had grown twice as fast as for those taking Zocor alone.

30. Dr. Steven E. Nissen, the chairman of cardiology at the Cleveland Clinic, called the results "shocking." Dr. Nissen told the *New York Times*, "This is as bad a result for the drug as anybody could have feared." Dr. Nissen, described as a widely published researcher and senior consulting editor to the Journal of the American College of Cardiology, added that millions of patients may be taking a drug that does not benefit them, raising their risk of heart attacks and exposing them to potential side effects. He recommended that patients not be given prescriptions for Zetia unless all other cholesterol drugs have failed.

31. Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Rep. Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, sent a letter to Merck and Schering-Plough on January 16, 2008, requesting documents concerning the Enhance study and the marketing of Vytorin.

D. Merck and Schering-Plough Delayed the Results of the Enhance Study for Nearly Two Years

32. The Enhance study was completed in April 2006. In June 2006, a Schering-Plough executive told investors that the Enhance data would be ready by year-end. Defendants released

the results on January 14, 2008 only after media reports in November on the delays, and a letter from Reps. Dingell and Stupak dated December 11, 2007, which demanded information on the delay. The letter from the Members of Congress also noted that Defendants had not registered the Enhance study on clinicaltrials.gov (a registry of federally and privately supported clinical trials maintained by the federal government) until October 2007, 18 months after the study's end.

33. In addition to delaying the results of the study, Defendants altered the study's primary endpoints during the course of the study. The Enhance study's original primary endpoints were the growth of plaque in three points in the carotid and femoral arteries. However, on November 19, 2007, Defendants announced that the study was only measuring thickness of plaque at one place in the carotid artery, and was not reporting results from the femoral artery.

34. In addition, according to a letter from Reps. Dingell and Stupak, the advisory panel created to advise Defendants on the Enhance data did not include the study's primary investigator, Dr. John Kastelein. According to the letter, Dr. Kastelein was not even at the meeting where the panel recommended altering the study's endpoints.

35. Defendants maintained in a press release dated November 19, 2007 that the Enhance results were still un-blinded. However, Dr. Kastelein said in November 2007 that Schering-Plough and Merck controlled the raw data and raised questions about its accuracy, resulting in long delays. "There was friction and tension," he told the *New York Times.*

36. The *New York Times* also reported that the Enhance dropped some patients after tests showed elevated liver enzymes – a potential sign of organ damage. Schering-Plough would not disclose how many were dropped.

37. Merck and Schering-Plough previously suppressed other studies about Zetia which raised questions about liver damage caused by Zetia when used long term with statins. Partial results of these studies appeared on the FDA's website, but Defendants never published these studies, and the unpublished studies were not listed on drug trial registries where companies are to register the results of all drug trials ongoing after October 2002.

38. When applying for FDA approval of Zetia, Merck/Schering-Plough relied on trials lasting only 12 weeks, but even in those, 11 times as many people who took Zetia along with a statin subsequently had serious health problems, compared with those who took a statin alone.

E. Defendants' Misrepresentations and Omissions Concerning Zetia and Vytorin

39. From the time that the study was completed in April 2006, Defendants intensively marketed Zetia and Vytorin on television, radio, and in print media, spending more than $200 million on direct-to-consumer advertising through the first three quarters of 2006.

40. From April 2006 to the present, Defendants were aware that Zetia and Vytorin, compared to Zocor alone, failed to slow – and may even have contributed to – plaque formation in the arteries of those with high cholesterol.

41. Defendants heavily promoted, and continue to promote, Zetia and Vytorin's purported distinct mechanism of action as an advantage in treating high cholesterol, claiming overall health benefits as a result, including cardiovascular benefits.

42. Defendants' website for Vytorin states, "Everyone's cholesterol comes from 2 sources. And targeting both is an effective way to lower it. The good news is that you can target both sources with a product that helps block absorption of cholesterol from food *and* reduces the cholesterol that your body makes." The quoted paragraph linked to a web page titled "About Vytorin." The linked page on Defendants' Vytorin website states that Vytorin is the "only product that: helps block the absorption of cholesterol that comes from food, and reduces the cholesterol your body makes naturally. The result is that less bad cholesterol ends up in your bloodstream. *And that's good for your health*" (emphasis in original).

43. Defendants' website for Zetia is titled "A different way to fight cholesterol" (emphasis in original). It states, "ZETIA works differently," going on to contrast Zetia with statins, which work in the liver. It concludes, "ZETIA complements what you are already doing – whether it's diet and exercise or also taking a statin."

44. Neither the Vytorin nor the Zetia website contained or contain any reference to the results of the Enhance study.

45. The results of the Enhance study – known to Defendants – revealed that the benefits claimed by Defendants on their Zetia and Vytorin websites to be false. As Dr. Nissen told the *New York Times*, "Cholesterol lowering with [Zetia] might not provide the same benefits as statins for the same degree of cholesterol reduction." Another cardiologist also stated, "Statins have diverse effects beyond simple LDL cholesterol lowering, such as potent anti-inflammatory actions." The cardiologist added, "There has yet to be a clinical trial to show that ezetimibe [Zetia] improves clinical outcomes."

46. In a two-page advertisement taken out in the January 20, 2008 *New York Times* and re-run on January 23, 2008, Defendants acknowledged, but did not reveal the results of the Enhance study. They continued to imply that the purported benefits of Zetia and Vytorin were equivalent to cholesterol medications that slow the growth of fatty plaque in the arteries. The advertisement stated, "In fact, Zetia and Vytorin have been proven to lower LDL (bad) cholesterol along with diet [*sic*], in multiple clinical studies involving thousands of patients. Both the American College of Cardiology and the American Heart Association agree that lowering bad cholesterol is important." Elsewhere, the advertisement stated, "LDL is called 'bad cholesterol' because it can cause build up in the wall of your arteries and form plaque." However, the advertisement did not state that the Enhance study had shown that Vytorin did not slow – and may have contributed to – the growth of fatty plaque in the arteries.

47. On January 22, 2008, Defendants Merck & Schering-Plough announced they were suspending television advertising for Vytorin and Zetia.

48. Fred Hassan, the chairman and chief executive officer of Schering-Plough, gave an interview to the *New York Times* on April 14, 2007, in which he was asked, "How does your drug Zetia attack the cholesterol problem?" He answered,

> Cholesterol, including L.D.L.'s, are manufactured in the liver. Statins, which came into the market in 1987, work by interfering with that process in the liver. But Zetia, which was a major advance we achieved in 2002, prevents the absorption of bad cholesterol in the gastrointestinal tract. It's a separate mode of action. That's helpful for a whole bunch of people who don't tolerate statins very well.

Mr. Hassan made no mention of the Enhance study, which had been completed a year previously.

VI. FRAUDULENT CONCEALMENT

49. Plaintiffs were not and could not have been aware of Defendants' misconduct until Defendants released the results of the Enhance study on January 14, 2008. Defendants concealed the nature of their representations and omissions concerning Zetia and Vytorin by refusing to release the results of the study until nearly two years after its conclusion. Because of these and other acts of concealment, Plaintiffs could not have discovered the scheme alleged herein in the exercise of reasonable diligence.

VII. DEFENDANTS' MOTIVE

50. Defendants' motive in creating and operating the fraudulent scheme and RICO Enterprise described herein was fraudulently to obtain additional revenues from the marketing and sale of Zetia and Vytorin.

51. The fraudulent scheme was designed to, and did, cause Plaintiffs and Class Members to pay for Zetia and Vytorin prescriptions for cholesterol management when cheaper and effective treatments were available. In the absence of Defendants' improper conduct, Plaintiffs and the Classes would not have paid for such Zetia and Vytorin prescriptions.

VIII. USE OF THE MAILS AND WIRES

52. During the Class Period, Defendants used thousands of mail and interstate wire communications to create and manage their fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed physicians and victims across the country.

53. Defendants' use of the mails and wires to perpetrate their fraud involved thousands of communications throughout the Class period, including marketing and advertising materials touting the effectiveness of Zetia and Vytorin, such materials being sent to physicians and media outlets throughout the country; communications with health insurers and patients, including Plaintiffs and the Classes, inducing payments for Zetia and Vytorin to be made in reliance on misrepresentations concerning the safety and effectiveness of Zetia and Vytorin.

54. In addition, Defendants' corporate headquarters have communicated by United States mail, telephone, and facsimile with various physicians and consumers in furtherance of Defendants' scheme.

IX. CLASS ACTION ALLEGATIONS

55. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiff Edwards brings this action on behalf of herself and a Consumer Class, defined as:

> All individuals in the United States and its territories who, for purposes other than resale, purchased, reimbursed and/or paid for Vytorin, or Zetia prescribed in combination with a statin, during the period from April 1, 2006 through the present. For purposes of the Class definition, individuals "purchased" Vytorin if they paid some or all of the purchase price.

Excluded from the Consumer Class are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from the Class are any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

56. Additionally, Plaintiff ASEA brings this action on behalf of a Third Party Payer Class, defined as:

> All private, non-governmental entities in the United States and its territories that paid for or reimbursed all or part of the cost of Vytorin, or Zetia prescribed in combination with a statin, from April 1, 2006 to the present. Such entities include, but are not limited to, insurance companies, union health and welfare benefit plans, entities with self-funded plans that contract with a health insurance company or other entity to serve as a third-party claims administrator to administer their prescription drug benefits, private entities paid by any governmental entity (including a state Medicaid program) to provide prescription drug benefits on a capitated basis, and other organizations that paid for all or part of a Zetia or Vytorin prescription since April 1, 2006.

Excluded from the Third Party Payer Class are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from this Class are any individuals that belong to the Consumer Class, as defined above. Finally, also excluded from this Class are any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

57. Each of these Classes consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). The disposition of

the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court.

58. The claims of the representative Plaintiffs are typical of the claims of the Class each seeks to represent, as required by Rule 23(a)(3), in that the representative Plaintiffs are persons or entities who, like all Class members, purchased, reimbursed, and/or paid for Zetia or Vytorin. Such representative Plaintiffs, like all Class members, have been damaged by Defendants' misconduct, in that, among other things, they paid for Zetia or Vytorin as Defendants misrepresented the safety and efficacy of Zetia or Vytorin relative to the use of statins alone.

59. The factual and legal bases of Defendants' misconduct are common to all members of the Classes and represent a common thread of fraud and other misconduct resulting in injury to Plaintiffs and all members of each Class.

60. There are many questions of law and fact common to Plaintiffs and the Classes, and those questions predominate over any questions that may affect individual Class members, within the meaning of Rule 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

a. Whether Zetia and Vytorin are safe and effective in treating atherosclerosis;

b. Whether Zetia and Vytorin are safe and effective in treating high cholesterol, relative to other, cheaper alternatives;

c. Whether Defendants concealed material information from Plaintiff, members of the Classes, physicians, and the general public concerning the safety and efficacy of Zetia and Vytorin;

d. Whether Defendants engaged in a fraudulent and/or deceptive scheme of marketing and selling Zetia and Vytorin for treating high cholesterol and associated risk factors for heart attacks, such as atherosclerosis;

e. Whether it was the policy and practice of Defendants to prepare, fund and publish materials which contained false information and misrepresentations regarding the safety and efficacy of Zetia and Vytorin;

f. Whether Defendants are liable to the Class Members for damages for conduct actionable under the New Jersey Consumer Fraud Act;

g. Whether Defendants are liable to Class Members for damages for conduct actionable under the Uniform Deceptive Trade Practices Act;

h. Whether Defendants are liable to Class Members for damages for conduct actionable under the RICO statute;

i. Whether Defendants are liable to Class Members for damages for conduct actionable as common law fraud;

j. Whether Defendants unjustly enriched themselves at the expense of Class Members;

k. Whether Defendants engaged in a pattern or practice that directly caused Plaintiffs and Class Members to pay for Zetia and Vytorin prescriptions that were ineffective relative to other, cheaper alternatives;

l. Whether Class Members are entitled to compensatory damages and, if so, the nature and extent of such damages;

m. Whether Class Members are entitled to punitive damages and if so, the extent of such damages.

61. Plaintiffs will fairly and adequately represent and protect the interests of the Classes, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in the prosecution of nationwide class actions. Plaintiffs and their counsel are committed to the vigorous prosecution of this action on behalf of the Classes and have the financial resources to do so. Neither Plaintiffs nor counsel have any interests adverse to those of the Classes.

62. Plaintiffs and Class Members have suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, most members of the Classes likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law

and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.

X. TOLLING OF STATUTE OF LIMITATIONS

63. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and Class Members have been kept in ignorance of vital information essential to the pursuit of these clams, without any fault or lack of diligence on their part. Plaintiffs and Class Members could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of Plaintiffs' or the Classes' claims.

XI. CAUSES OF ACTION

FIRST CAUSE OF ACTION
(Violation of 18 U.S.C. § 1962(c))
(Against Defendants Merck and Schering-Plough Only)

64. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

65. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

66. MSP is an enterprise within the meaning of 18 U.S.C. § 1961(4), consisting of each of Defendants, including their employees and agents, and MSP. The Enterprise is an ongoing organization that functions as a continuing unit. The Enterprise was created and/or used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Enterprise.

67. The Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Zetia and Vytorin to thousands of individuals throughout the United States.

68. Defendants have exerted control over the Enterprise, and Defendants have participated in the operation or management of the affairs of the Enterprise, through the following actions:

a. Defendants have asserted direct control over the information and content disseminated to Plaintiffs, members of the Classes, and physicians regarding the efficacy of Zetia and Vytorin;

b. Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Plaintiffs, Class Members, and physicians throughout the United States; and

c. Defendants have placed their own employees and agents in positions of authority and control in the Enterprise.

69. Defendants have conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341 and 1343 (mail and wire fraud), as described above.

70. In implementing their fraudulent scheme, Defendants were aware that Plaintiffs and Class Members depend on the honesty of Defendants in representing the safety and medical efficacy of Zetia and Vytorin.

71. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) concealing from Plaintiffs, Class Members, and physicians, and the public the results of the Enhance study, which showed that Zetia and Vytorin were ineffective in slowing the growth of fatty plaque in the arteries; (b) deliberately misrepresenting the efficacy of Zetia and Vytorin in treating patients with high cholesterol; and (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiffs, and members of the Classes relied upon when choosing to prescribe or pay for Zetia and Vytorin when safer and effective treatments were available for treating high cholesterol.

72. Defendants' scheme was calculated to ensure that Plaintiffs and the Classes would pay for Zetia and Vytorin despite cheaper and effective alternatives.

73. Each of Defendants' fraudulent mailings and interstate wire transmissions constitute "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

74. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiffs and the Classes.

75. The above described racketeering activities amounted to a common course of conduct intended to deceive Plaintiffs and the Classes. Defendants' criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiffs and the Classes. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and the members of the Classes. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiffs and Class Members.

76. The pattern of racketeering activity alleged herein and the Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Enterprise.

77. Plaintiffs and members of the Classes have been injured in their property by reason of these violations in that Plaintiffs and members of the Classes have made billions of dollars in payments for Zetia and Vytorin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

78. Plaintiffs and members of the Classes relied to their detriment on Defendants' fraudulent misrepresentations and omissions.

79. Plaintiffs' and members of the Classes' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

80. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs and the Class for three times the damages Plaintiffs and Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

SECOND CAUSE OF ACTION
Violation of 18 U.S.C. § 1962(d) By Conspiring To Violate 18 U.S.C. § 1962(c)
(Against Defendants Merck and Schering-Plough Only)

81. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

82. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

83. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Enterprise described previously through a pattern of racketeering activity.

84. As demonstrated in detail above, Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs and the Classes of money.

85. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

86. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs and Class Members have been and are continuing to be injured in their business or property as set forth more fully above.

87. Defendants have sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346; and

c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1343 and 1346.

88. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue unless injunctive relief prohibiting Defendants' illegal acts constituting a pattern of racketeering activity is fashioned and imposed by the Court.

THIRD CAUSE OF ACTION
Violations of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.
(Against All Defendants)

89. Plaintiffs incorporate by reference all preceding paragraphs.

90. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of the Class against Defendants.

91. The unfair and deceptive acts and practices of Defendants have directly, foreseeably, and proximately caused or will cause damages and injury to Plaintiffs and the members of the Class.

92. The actions and failures to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and efficacy of Zetia and Vytorin, and the above described course of fraudulent conduct and fraudulent concealment, constitute acts, uses, or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*

93. Physicians relied upon Defendants' misrepresentations and omissions in prescribing Zetia and Vytorin, despite the availability of cheaper and effective alternatives. Plaintiffs and the Classes were damaged by paying for these prescriptions.

94. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and Class Members are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit.

FOURTH CAUSE OF ACTION
(Uniform Deceptive Trade Practices Act)
(Against All Defendants)

95. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

96. If the Court does not permit Plaintiffs to pursue the Third Cause of Action on behalf of a national class, in the alternative, Plaintiffs assert this claim for violations of the Uniform Deceptive Trade Practices Act ("UDTPA"), which prohibits "[r]epresenting that goods . . . have

sponsorship, approval, characteristics, . . . uses, [or] benefits . . . that they do not have," on behalf of a subclass composed of all Class Members who reside in the 22 states who have enacted these provisions of the UDTPA (listed in Paragraph 98).

97. Defendants engaged in deceptive trade practices in violation of the 22 state consumer protection statutes that incorporate the provisions of the UDTPA quoted above, by, *inter alia*, (a) withholding the results of the Enhance study for over almost two years; (b) deliberately misrepresenting the efficacy of Zetia and Vytorin relative to the use of statins alone; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiffs, and Class Members relied upon when choosing to prescribe or pay for Vytorin or Zetia to treat conditions better treated by statins alone; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Vytorin or Zetia.

98. Defendants have violated the deceptive trade practices statutes of the 22 states that incorporate the provisions of the UDTPA quoted above, as follows:

a. Defendants have engaged in deceptive trade practices in violation of Ala. Code § 8-19-5, *et seq.*;

b. Defendants have engaged in deceptive trade practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in deceptive trade practices in violation of Cal. Civ. Code § 1770 *et seq.*;

d. Defendants have engaged in deceptive trade practices in violation of 6 Del. C. § 2532, *set seq.*;

e. Defendants have engaged in deceptive trade practices in violation of Ga. Code Ann. §§ 10-1-372, *et seq.*, 10-1-393 *et seq.*, and 26-2-29 *et seq.*;

f. Defendants have engaged in deceptive trade practices in violation of Haw. Rev. Stat. § 481A-3, *et seq.*;

g. Defendants have engaged in deceptive trade practices in violation of Idaho Code § 48-603 *et seq.*;

h. Defendants have engaged in deceptive trade practices in violation of 815 Ill. L.C.S. § 510/2 *et seq.*;

i. Defendants have engaged in deceptive trade practices in violation of 10 Me. Rev. Stat. Ann. § 1212, *et seq.*;

j. Defendants have engaged in deceptive trade practices in violation of Mich. Comp. L. Ann. § 445.903 *et seq.*;

k. Defendants have engaged in deceptive trade practices in violation of Minn. Stat. Ann. § 325D.44 *et seq.*;

l. Defendants have engaged in deceptive trade practices in violation of Miss. Code Ann. § 75-24-5 *et seq.*;

m. Defendants have engaged in deceptive trade practices in violation of Neb. Rev. Stat. §§ 81-2,285 *et seq.*, 87-302 *et seq.*;

n. Defendants have engaged in deceptive trade practices in violation of N.H. Rev. Stat. § 358-A:2 *et seq.*;

o. Defendants have engaged in deceptive trade practices in violation of N.M. Stat. Ann. § 57-12-2 *et seq.*;

p. Defendants have engaged in deceptive trade practices in violation of Ohio Rev. Code § 4165.02 *et seq.*;

q. Defendants have engaged in deceptive trade practices in violation of Or. Rev. Stat. § 646.608 *et seq.*;

r. Defendants have engaged in deceptive trade practices in violation of 10 Penn. Stat. § 162.15 *et seq.* and 73 Penn. Stat. § 201-2 *et seq.*;

s. Defendants have engaged in deceptive trade practices in violation of R.I. Gen. Laws § 6-13-1.1 *et seq.*;

t. Defendants have engaged in deceptive trade practices in violation of Tenn. Code Ann. § 47-18-104 *et seq.*;

u. Defendants have engaged in deceptive trade practices in violation of Tex. Bus. & Comm. Code § 17.46, *et seq.*;

v. Defendants have engaged in deceptive trade practices in violation of Utah Code § 13-11a-3 *et seq.*;

w. Defendants have engaged in deceptive trade practices in violation of W.Va. Code § 46A-6-102 *et seq.*

99. To this date, Defendants continue to engage in the foregoing unlawful practices in violation of the UDTPA and the deceptive trade practices statutes of the 22 states that incorporate the UDTPA.

100. Plaintiffs and Class Members suffered actual damages as a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices.

FIFTH CAUSE OF ACTION
(Common Law Fraud)
(Against All Defendants)

101. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

102. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of each Class against Defendants.

103. Defendants made misrepresentations and omissions of facts material to Plaintiffs' and Class Members' decisions to purchase Zetia and Vytorin by, *inter alia*, (a) concealing from Plaintiffs, Class Members, and physicians, and the public the results of the Enhance study, which showed that Zetia and Vytorin were ineffective in slowing the growth of fatty plaque in the arteries; (b) deliberately misrepresenting the safety and efficacy of Zetia and Vytorin in treating patients with high cholesterol; and (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiffs, and members of the Classes relied upon when choosing to prescribe or pay for Zetia and Vytorin when safer and effective treatments were available for treating high cholesterol.

104. Defendants knew at the time that they made these misrepresentations and omissions that they were false.

105. Defendants intended that Plaintiffs and the Class Members would rely on these misrepresentations and omissions of material fact, so that Plaintiffs and Class Members would purchase Zetia and Vytorin.

106. Plaintiffs and Class Members reasonably relied upon Defendants' misrepresentations and omissions of material fact. Plaintiffs and Class Members had no reason to doubt the veracity or scientific validity of the information Defendants promoted through their marketing and sales strategies.

107. Defendants' misrepresentations and omissions of material fact directly and proximately caused Plaintiffs' and the Classes' damages.

108. By virtue of the fraud they perpetrated on Plaintiffs and the Classes, Defendants are jointly and severally liable to Plaintiffs and Class Members for all damages Plaintiffs and Class Members have sustained, plus punitive damages, plus the cost of this suit, including attorneys' fees.

SIXTH CAUSE OF ACTION
(Unjust Enrichment)
(Against All Defendants)

109. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

110. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of each Class against Defendants.

111. As the intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiffs and Class Members made for Zetia and Vytorin.

112. In exchange for the payments they made for Zetia and Vytorin, and at the time they made these payments, Plaintiffs and the Classes expected that the drug was a safe and medically effective treatment for the condition, illness, disease, disorder, or symptom for which it was prescribed.

113. Defendants have voluntarily accepted and retained these payments, with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and the Classes paid for Zetia and Vytorin when they otherwise would not have done so. By its improper and wrongful conduct

described herein, Defendants were unjustly enriched at the expense of Plaintiffs and the members of the Classes.

114. It would be inequitable for Defendants to retain the profits, benefits, and other compensation it obtained through its wrongful acts. Plaintiffs and the Classes are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Classes demand judgment against Defendants in each claim for relief, jointly and severally, as follows:

115. On Plaintiffs' and the Classes' RICO claims, three times the damages Plaintiffs and the Class have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

116. On Plaintiffs' and the Consumer Classes' New Jersey Consumer Fraud Act claim, compensatory damages, three times the damages Plaintiffs and the Class have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

117. On Plaintiffs' and the Classes' Uniform Deceptive Trade Practices Act claim as incorporated in the deceptive trade practices statutes of 22 states, all measures of damages allowable under such statutes, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including attorneys' fees;

118. On Plaintiffs' and the Classes' common law fraud claim, compensatory damages, punitive damages, such amounts to be determined at trial, plus Plaintiffs' costs in this suit, including all reasonable attorneys' fees;

119. On Plaintiffs' and the Classes' claim for unjust enrichment, recovery in the amount of Plaintiffs' and the Class' payment for Zetia and Vytorin, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including all reasonable attorneys' fees;

120. Awarding Plaintiffs and the Classes other appropriate equitable relief;

121. Awarding Plaintiffs their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

122. Awarding Plaintiffs and the Classes such other and further relief as may be just and proper under the circumstances.

XIII. DEMAND FOR JURY TRIAL

123. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury on all issues so triable.

Dated: January 23, 2008

Respectfully submitted,

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

By: _____
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